AMENDMENT TO CLAIMS:

Please amend the claims as follows:

1. **(Currently Amended)** A ~~lidless~~ device for detecting one or more target ligands in a sample, comprising:

a nonporous surface comprising one or more particles immobilized to said surface,

wherein said particles comprise antibodies or fragments thereof immobilized to said particles,

wherein the antibodies or fragments thereof bind specifically to said one or more target ligands, ~~and~~

wherein said particle size range is from 1 nm to 5 μm, wherein said surface is a textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5 mm from said surface, and

wherein said assay device comprises a capillary space between said nonporous surface and a second surface spaced at a capillary forming distance from said nonporous surface.

2. **(Cancelled)**
3. **(Cancelled)**
4. **(Currently Amended)** An assay device according to claim [[3]] 1, wherein one or more of said particles are entrapped within depressions and/or between protrusions on the textured surface.
5. **(Previously Presented)** An assay device according to claim 1, wherein said particles are selected from the group consisting of latex particles, silica particles, zirconia particles, alumina particles, titania particles, ceria particles, metal sol particles, and polystyrene particles.
6. **(Cancelled)**
7. **(Cancelled)**
8. **(Currently Amended)** The assay device according to claim [[6]] 1, wherein the capillary forming distance is from 0.01 mm to 0.2 mm.

REMARKS

The following remarks are in response to the Examiner's Office Action mailed on September 16, 2009. Claims 1, 3-6 and 8 are pending. Claims 1, 4 and 8 have been amended. Claims 3 and 6 have been cancelled. Claim 1 has been amended to incorporate all elements of claims 3 and 6. Claims 4 and 8 have been amended to change dependency from cancelled claims 3 and 6 to claim 1, respectively. No new matter is introduced, and entry thereof is respectfully requested.

Reconsideration is respectfully requested in light of the following remarks.

Claim Rejections – 35 USC § 112

The Examiner has rejected claims 1, 3-6 and 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection, as the term lidless is clear and it is supported and described by the specification (See, for example, Figure 12 and paragraphs [0212] and [0215] in which lidless devices contain capillary spaces formed by stops and/or energy directors) . However, in the interest to expedite prosecution, without acquiescing to the Examiner's rejection, Applicants have removed the term lidless from claim 1. Nevertheless, lidless devices are within the scope of the invention. Withdrawal of this rejection is respectfully requested.

Claim Rejections – 35 USC § 102

A. The Examiner has rejected claims 1 and 3-6 under 35 U.S.C. 102(b) as being anticipated by Findlay et al. (USP 5,514,550). Applicants respectfully traverse. However, in the interest of advancing prosecution without acquiescence to the Examiner's rejection, Applicants hereby opt to amend claim 1.

Amended claim 1 is not anticipated by Findlay et al., because Findlay et al. does not disclose each and every limitation of the claimed invention. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See MPEP § 2131.

First, amended claim 1 recites "wherein the antibodies or fragments thereof bind specifically to said one or more target ligands". Findlay et al. does not disclose antibodies or fragments thereof that bind specifically to one or more binding targets. Findlay discloses in column 7, lines 18- 29 that a second probe is labeled with a moiety, such as an antibody, that provides for a detectable dye on the test article. The antibodies disclosed in Findlay do not bind specifically to the target as they are indirectly attached to the target via an oligonucleotide probe (i.e., the second probe). It is well understood in the art, that when an antibody "binds specifically to a target" it does so through direct binding with the target via its variable structure (See Janeway-Travers, Immuno Biology The Immune System in Health and Disease, Chapter 3 (3rd ed. 1997). Thus, Findlay et al. does not disclose a device with antibodies as claimed in claim 1.

Second, amended claim 1 recites "wherein said surface is a textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5 mm from said surface". The Examiner alleges that "[t]he surface of Findlay et al. would have been expected to have at least one depression/protrusion between 1 nm and 0.5mm as a manufacturing imperfection." However, the Examiner provides no basis for this assumption. Paragraph [0103] of the instant application provides examples of protrusions and depressions. This paragraph states "[f]or example, surfaces composed of posts, grooves, pyramids, and the like referred to as protrusions; or holes, slots, waffled patterns and the like, referred to as depressions may be utilized." A person of ordinary skilled in the art would not consider the alleged imperfection in the surfaces described by Findlay et al. as the features claimed in claim 1. Furthermore, there is no disclosure or suggestion in Findlay et al. that the alleged depressions and/or protrusions extended between 1 nm and 0.5 mm from said surface. Thus, Findlay et al. also does not disclose a device comprising a textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5 mm from the surface.

Third, amended claim 1 recites "wherein said assay device comprises a capillary space between said nonporous surface and a second surface spaced at a capillary forming distance from said nonporous surface." The Examiner incorrectly states, referring to the disclosure in Findlay et al., that "it would have been inherent the two sheets sandwiching the probe would be a capillary distance apart because if the sheets were not a capillary distance apart, the fluid would not flow and contact the probes making the device inoperable." The Examiner is

mischaracterizing the disclosure in Findlay et al. Findlay et al. discloses the use of a sandwich assay to capture and detect a target nucleic acid. A "sandwich assay" as known in the art uses "two probes to sandwich the nucleic acid of interest therebetween in a three part hybridized product" (See Column 1, lines 39-42). One of the probes used in Findlay's sandwich assay is a water-insoluble nucleic acid probe attached to an article substrate (See Column 1, lines 45-67, and Column 3 lines 36-38). The article substrates described in Findlay et al. do not require a capillary distance between two surfaces to operate as stated by the Examiner in the Office Action. For example, Figures 1-3 show devices that do not contain a capillary distance between a first and a second surface. The fact that the article substrates from Findlay et al. do not require a capillary distance between a first and a second surface to operate is shown in the Example sections. The assays in Example 1 and 2 use a "flow through" procedure whereby the water-insoluble probe is immobilized on a filter membrane located in a test well. Hybridization of the target nucleic acid occurs followed by washing water-soluble materials through the filter membrane (See Column 10 lines 35-40, Column 11 lines 62-66 and Column 12 lines 31-49). In Example 3, Findlay et al. uses a "flow by" device in which reagents are forced into a pouch with a pipette tip to be in contact with the water-insoluble probe before exiting the pouch (See Column 10 lines 43-45 and Column 14 lines 51-55). Thus, contrary to the Examiner's assertion the article substrates described in Findlay et al. it do not inherently have two sheets at a capillary distance apart.

Thus, at least for the reasons stated above, Findlay et al. fails to disclose each and every limitation of claim 1. Therefore, this reference fails to anticipate the claimed invention. Withdrawal of this rejection is thus respectfully requested.

B. Further, the Examiner has rejected claims 1 and 3-5 under 35 U.S.C. 102(b) as being anticipated by Wu et al. Applicants respectfully traverse. However, in the interest of advancing prosecution without acquiescence to the Examiner's rejection, Applicants hereby opt to amend claim 1.

Amended claim 1 is not anticipated by Wu et al., because Wu et al. does not disclose each and every limitation of the claimed invention. Like in Findlay et al, Wu et al. does not disclose "antibodies or fragments thereof that bind specifically to one or more binding targets". Wu et al. discloses in column 11, lines 45-50 that primers are labeled with a specific binding moiety, such

as antibody, that can be detected by a detectable receptor for the specific binding moiety. Like in Findlay et al., the antibodies disclosed in Wu et al. do not "bind specifically to the target" as they are indirectly attached to the target via an oligonucleotide probe (i.e., primers). As described above, it is well understood in the art, that when an antibody "binds specifically to a target" it does so through direct binding with the target via its variable structure (See Janeway-Travers, Immuno Biology The Immune System in Health and Disease, Chapter 3 (3rd ed. 1997). Thus, Wu et al. does not disclose a device with antibodies as claimed in claim 1.

Second, amended claim 1 recites "wherein said surface is a textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5 mm from said surface". The Examiner alleges that "[t]he surface of Wu et al. would have been expected to have at least one depression/protrusion between 1 nm and 0.5mm as a manufacturing imperfection." Again, the Examiner provides no basis for this assumption. As discussed above, paragraph [0103] of the instant application provides examples of protrusions and depressions, e.g., "surfaces composed of posts, grooves, pyramids, and the like referred to as protrusions; or holes, slots, waffled patterns and the like." A person of ordinary skilled in the art would not consider the alleged imperfection in the surfaces described by Wu et al. as the features claimed in claim 1. Furthermore, there is no disclosure or suggestion in Wu et al. that the alleged depressions and/or protrusions extended between 1 nm and 0.5 mm from said surface. Thus, Wu et al. does not disclose a device comprising a textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5 mm from the surface.

Third, amended claim 1 recites "wherein said assay device comprises a capillary space between said nonporous surface and a second surface spaced at a capillary forming distance from said nonporous surface." The Examiner acknowledges in the Office Action that Wu et al. "is silent to placing a second surface at a capillary distance from the nonporous surface". Thus, Wu et al. does not disclose a device comprising a capillary space between a nonporous surface and a second surface spaced at a capillary forming distance from the nonporous surface.

Thus, at least for the reasons stated above, Wu et al. fails to disclose each and every limitation of claim 1. Therefore, this reference fails to anticipate the claimed invention. Withdrawal of this rejection is thus respectfully requested.

Claim Rejections – 35 USC § 103

A. The Examiner has rejected claim 6 and 8 under 35 U.S.C. 103(a) as being unpatentable over Wu et al. in view of Oosta et al. (USP 5,478,751).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2142, citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants respectfully submit that the criteria for a *prima facie* case of obviousness are not met because the combined teachings of Wu et al. and Oosta et al. do not suggest all elements of claim 1 from which claims 6 and 8 depend. As described above, Wu et al. does not disclose a device comprising "antibodies or fragments thereof that bind specifically to one or more binding targets" and "wherein said surface is a textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5 mm from said surface".

This fundamental deficiency is not cured by Oosta et al. Oosta et al. is merely cited for its disclosure on a capillary flow device.

Furthermore, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine teachings of Wu et al. and Oosta et al. to reach the claimed invention. Wu et al. is predominantly addressing the detection of nucleic acid using a sandwich assay in which one of the probes is a water-insoluble capture probe. As mentioned by the Examiner Wu et al. is silent with respect to the use of devices comprising a capillary distances between a nonporous surface and a second surface. Oosta et al. describes improved capillary devices that are self-venting (See Abstract and Column 1 lines 58-67). There are no teachings or suggestions in Oosta et al. to have a device comprising a textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5 mm from said surface. Oosta et al. describes a laminated device formed from hydrophobic polymer sheets. Thus, one of ordinary skilled in the

art would not combine the sandwich assay described in Wu et al. - which is silent and does not require, disclosed or even suggest the use of capillary device - with the self venting capillary device in Oosta to reach to the claim device. Furthermore, if one of the problems to be solved is one of providing a more uniform layer of antibody within the device as described in paragraph [0104] of the instant application for example, there is no reason to combine the teaching in Oosta et al. with Wu et al. If there is no suggestion or motivation of the claim limitations in the cited references, there can not be a reasonable expectation of success.

Therefore, at least in view of the reasons stated above a *prima facie* case of obviousness has not been established. Withdrawal of the rejection under 35 U.S.C. §103(a) is therefore respectfully requested.

B. In addition, the Examiner has rejected claim 8 under U.S.C. 103(a) as being unpatentable over Findlay et al.

Applicants respectfully submit that the criteria for a *prima facie* case of obviousness are not met because the teachings of Findlay et al. do not suggest all elements of claim 1 from which claims 8 depend. As described above, Findlay et al. does not disclose a device comprising particles comprising antibodies or fragments thereof, "wherein the antibodies or fragments thereof bind specifically to said one or more target ligands", "wherein said surface is a textured surface comprising one or more depressions and/or protrusions extending between 1 nm and 0.5 mm from said surface", and "wherein said assay device comprises a capillary space between said nonporous surface and a second surface spaced at a capillary forming distance from said nonporous surface" as claimed in claim 1. Therefore, in view of the missing limitations in the reference cited by the Examiner, a *prima facie* case of obviousness has not been established. Claim 8 depending from claim 1 and reciting additional elements is, thus, also not obvious over Findlay et al.

Withdrawal of this rejection is respectfully requested.